Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2000 list were published in the Federal register in December 1999.

New Approvals

ANADA Number: 200-244

Pioneer Product:	200-033
Trade Name:	Tucoprim® Powder
Ingredients:	Sulfadiazine, trimethoprim
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	October 22, 1999
Status:	Prescription only
Route:	Oral
Species:	Equine
Dose Form:	Powder
Concentration:	Sulfadiazine 67 mg and trimethoprim 333 mg per gram of powder
Indications:	For control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.

21CFR 520.2613

NADA Number: 141-103

Trade Name:	SevoFlo™
Ingredients:	Sevoflurane
Sponsor:	Abbott Laboratories
Approval Date:	November 17, 1999
Status:	Prescription only
Route:	Inhalant
Species:	Dogs
Dose Form:	Liquid (solution)
Concentration:	99.9% per mL
Indications:	For induction and maintenance of general anesthesia.
Exclusivity:	5 years

21CFR 529.2150

Supplemental Approvals

NADA Number: 140-976

This supplemental application provides for the finalization of NAS/NRC/DESI review of Neomycin Sulfate Type A Medicated Articles.

Trade Name:	Neomix® 325 Medicated Premix / Neomix® AG 325 Medicated Premix
Ingredients:	Neomycin sulfate
Sponsor:	Pharmacia & Upjohn Co.
Approval Date:	November 3, 1999
Status:	Over-the-counter
Route:	Oral
Species:	Swine, sheep, cattle (excluding veal calves), goats
Dose Form:	Type A Medicated Article to make Type B and C medicated feeds.
Concentration:	325 grams per pound
Indications:	For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate.
Tolerance:	21CFR 556.430: A tolerance of 7.2 ppm is established for residues of parent neomycin (marker residue) in uncooked edible kidney (target tissue), 7.2 ppm in fat, 3.6 ppm in liver, 1.2 ppm in muscle of cattle, swine, sheep, and goats. A tolerance of 0.15 ppm is established for neomycin in milk.
Withdrawal:	Cattle – 1 day Sheep – 2 days Swine and goats – 3 days

21CFR 558.4 and 558.364

Change of Sponsor Address

Hoechst Roussel Vet,
Perryville Corporate Park III
P.O. Box 4010
Clinton, NJ 08809-4010

Addition of Patent Number

NADA Number: 141-061

Patent Number: 6,001,822 Expiration Date: Dec. 14, 2016

Suitability Petition Action

Number:	99P-4167/CP1
Sponsor:	A & G Pharmaceuticals, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, Phenylbute™, Phoenix Scientific Inc., NADA 091-818 by the following characteristic: the proposed generic product will have a dosage form as a powder as opposed to the pioneer product which is a tablet.
Action:	Approved on December 7, 1999

Number:	99P-5328/CP1
Sponsor:	Tyler Group, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, prednisolone, which differs from the pioneer product, PrednisTab®, Lloyd, Inc., NADA 140-921 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.
Action:	Filed on December 3, 1999

Number:	99P-5329/CP1
Sponsor:	Tyler Group, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, furosemide, which differs from the pioneer product, Lasix®, Hoechst Roussel Vet, NADA 34-621 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.
Action:	Filed on December 3, 1999

Number:	99P-5330/CP1
Sponsor:	Tyler Group, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, enalapril maleate, which differs from the pioneer product, Enacard® Tablets, Merial Ltd., NADA 141-015 by the following characteristics: the proposed generic product will have a dosage form as a palatable chewable tablet as opposed to the pioneer product which is a tablet.
Action:	Filed on December 3, 1999

Number:	99P-5331/CP1
Sponsor:	PharmX, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug, phenylbutazone, which differs from the pioneer product, PhenylBute™, Phoenix Scientific Inc., NADA 91-818 by the following characteristics: the proposed generic product will have a dosage form as palatable pellets as opposed to the pioneer product which is a tablet.
Action:	Filed on December 13, 1999

Amendments of a Final Rule

The final rule published in the Federal Register of September 17, 1996 (61 FR 48829), added Section 522.147 (21 CFR 522.147) and incorrectly stated that Pfizer, Inc. was the sponsor of NADA 141-033. FDA is amending Section 522.147 to correctly identify Orion Corp. as the sponsor.

The final rule published in the Federal Register of July 2, 1999 (64 FR 35923) reflected approval of Schering-Plough Animal Health Corp.'s NADA 140-951. The final rule added 21 CFR 556.175 and 558.198 to reflect the approval, but failed to amend Section 558.4 (21 CFR 558.4) to add an entry stating the maximum Type B level and assay limits. At this time, Section 558.4 is amended in paragraph (d) in the table "Category I" accordingly.